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Effectiveness and cost-effectiveness of an educational intervention for practice teams to deliver problem focused therapy for insomnia: a pilot cluster randomised trial

Submission date
27/06/2008

Recruitment status
No longer recruiting

Registration date
31/07/2008

Overall study status
Completed

Last Edited
05/03/2014

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title

Study objectives
Sleep problems are common, affecting two fifths of the population. Poor sleep (insomnia) is linked with psychological problems such as depression and physical problems such as high blood pressure, weight gain and heart disease. Many of those affected seek help from GPs whose response is often limited to sleep hygiene advice (a bedtime routine avoiding caffeine, alcohol, cigarettes or other stimulants) or prescription of sleeping pills (hypnotics) neither of which has been shown to be effective in the long term. Drugs for sleep difficulties are ineffective long term and probably do more harm than good, particularly in the elderly. Psychological /behavioural methods for managing sleep problems, termed cognitive behavioural therapy for insomnia (CBTi) have been shown to be effective and cost-effective when delivered by specialists but have not been fully evaluated in a general practice setting where they are most likely to be needed and most appropriately delivered.

Hypothesis:
Education for primary care teams in problem focused therapy for patients presenting to primary care with insomnia leads to better sleep outcomes for patients compared to treatment as usual with sleep hygiene up to three months from the beginning of treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The North Nottingham Local Research Ethics Committee, approval received on the 16th September 2008 (ref: 08/H0406/128).

Primary study design
Interventional

Study design
Cluster randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Insomnia

Interventions
We will undertake a pilot cluster randomised controlled trial (RCT) in which general practices are the unit of randomisation and where data will be collected from patients. Recruited general medical practices will be randomised to one of two arms; intervention consisting of education of primary care teams to use problem focused therapy for insomnia comprising sleep assessment tools (sleep diaries and Insomnia Severity Index) and modified cognitive behavioural therapy for insomnia (mCBTi); or a control arm using treatment as usual (TAU).

Patients will be involved in the study for a total of 13 weeks. Study outcomes will be measured at baseline, 4 weeks, 8 weeks and 13 weeks. Follow-up assessments will be performed using a telephone call at 2 weeks after the first treatment and self-completed postal questionnaires at all other timepoints. Non-responders will be telephoned 1 week after mailing the follow-up

questionnaire on up to two occasions and posted a replacement questionnaire with a reminder letter if there is still no response at 2 weeks.

Please use the following contact details to request a patient information sheet:
Miss Tanefa Apekey
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REST Project
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Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Global sleep quality as measured by PSQI at 0, 4, 8 and 13 weeks.

Key secondary outcome(s)
Measured at 0, 4, 8 and 13 weeks:
1. The effect of the intervention on sleep outcome measures assessed with PSQI and sleep diaries:
1.1. Self reported sleep onset latency (SOL): how long it takes to fall asleep
1.2. Wake time after sleep onset (WASO): total hours awake at night after one has fallen asleep
1.3. Total time in bed (TIB)
1.4. Sleep efficiency (SE). Sleep efficiency, expressed as a percentage, is calculated as follows: SE = (100- [(SOL + WASO/TIB) x 100])
2. Daytime sleepiness (Epworth Sleepiness Scale)
3. Anxiety and depression using the generic Beck Depression Inventory
4. Health-related quality of life using EuroQol EQ-5D
5. Frequency of use and mean dose of hypnotic medication

Patients will also keep a Data Record Book (DRB) to record any adverse effects that participants might experience during the treatment period.

Completion date
30/08/2009

Eligibility

Key inclusion criteria
1. At least 18 years old, either sex
2. Difficulty initiating and/or maintaining sleep for one month or more verified by Pittsburgh Sleep Quality Index (PSQI) score of greater than or equal to 5
3. New presentations with insomnia and existing patients on long term hypnotics

4. Points 1 - 3 above and sleep disrupted by painful conditions
5. Points 1 - 3 above and moderate/mild depression measured by the Beck Depression Inventory (BDI) (score 11 - 30)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Current or previous illicit substance or alcohol abuse
2. Pregnant or planning pregnancy in the next 12 months
3. Psychotic illness and severe depression defined by a BDI score greater than or equal to 31
4. Documented or active symptoms of sleep disruptive comorbid conditions, e.g. restless legs syndrome and any type of parasomnia
5. Obstructive sleep apnoea
6. Terminal illness
7. Inability to consent

Date of first enrolment
01/09/2008

Date of final enrolment
30/08/2009

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Professor of Primary Care, University of Lincoln
Lincoln
United Kingdom
LN6 7TS

Sponsor information

Organisation
Lincolnshire Primary Care Trust (UK)

Funder(s)

Funder type
Government

Funder Name
The Health Foundation (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	treatment fidelity results	01/01/2014		Yes	No
Protocol article	protocol	26/01/2009		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes